4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-D-0674]

Guidance for Industry: Food and Drug Administration Records Access Authority Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act." The guidance provides updated information pertaining to FDA's authority to access and copy records relating to food. It is a revision of FDA's November 2005 guidance entitled "Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance."

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Outreach and Information Center, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Center for Food Safety and Applied Nutrition (HFS-607), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1611.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act." This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of February 23, 2012 (77 FR 10753), we made available a draft guidance for industry entitled "FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act" and gave interested parties an opportunity to submit comments by May 23, 2012, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance. Other than providing further information on where to find guidance on the procedural steps for FDA staff to follow when accessing records under sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 21 U.S.C. 374, respectively), we are issuing the guidance with a few minor

changes. The guidance announced in this notice finalizes the draft guidance dated February 2012.

II. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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